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EXAMINER	
TRAN, MY CHAU T	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 05/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/944,083	LEFKOWITZ ET AL.	
	Examiner	Art Unit	
	MY-CHAU T TRAN	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-16 and 44-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-16 and 44-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/18/03 has been entered.

Status of Claims

2. Applicant's amendment filed 10/2/03 is acknowledged and entered. Claims 27-43 have been canceled. Claims 7, and 16 have been amended. Claims 50-51 have been added.

3. Claims 1-6 have been canceled by the amendment filed on 3/25/03.

4. Claims 7-26, and 44-51 are pending.

Priority

5. Applicant's claim for domestic priority under 35 U.S.C. 120 to US Patent Application serial no. 09/145,015, which is filed 9/1/1998, is acknowledged.

6. Applicant's specification amendment of page 1 filed 10/2/03 has been entered.

Oath/Declaration

7. The A new oath or declaration filed 12/17/03 is acknowledged and entered.

8. Claims 7-16, and 44-51 are treated on the merit in this Office Action.

Withdrawn Objections and /or Rejections

9. The rejection under 35 USC 103(a) as being unpatentable over Sundberg et al. (US Patent 5,624,711) in view of Wang et al. (US Patent 5,922,617) for claims 7-14, 16-23, 25-26, and 44-49 has been withdrawn in view of applicant amendment to Claims 7 and 16.

10. The rejection under 35 USC 103(a) as being unpatentable over Sundberg et al. (US Patent 5,624,711) in view of Wang et al. (US Patent 5,922,617) and further in view of Gleason et al. (US Patent 5,561,097) for claims 7-26, and 44-49 has been withdrawn in view of applicant amendment to Claims 7 and 16.

New Rejections – Necessitated by Amendment

Claim Rejections - 35 USC § 112

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 7-26, and 44-51 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (This is a new matter rejection.)

The presently claimed method of producing an array briefly recites the method steps of "a) providing a substrate having a surface displaying olefin functional groups by contacting said surface with a derivatizing composition comprising at least a first silane having an olefin functional group; b) converting said olefin functional groups to ligand reactive functional groups; and c) contacting said surface with said at least two different polymer ligands to covalently bond to said surface and produce said array".

The recitation of '*contacting said surface with a derivatizing composition comprising at least a first silane having an olefin functional group*' claimed in claims 7 and 16, have no clear support in the specification and the claims as originally filed. The specification in page 9 disclosed that the derivatizing composition comprise a first silane that is a derivatizing agent and a second silane that includes an olefinic functionality (paragraph [43], line 1-3) is not support for '*a derivatizing composition comprising at least a first silane having an olefin functional group*'. Because the narrow limitation of the specification recites that the derivatizing composition comprise a first silane that is a derivatizing agent and a second silane that includes an olefinic functionality, it does not support the broad limitation of the claim, which recites that "*a derivatizing composition comprising at least a first silane having an olefin functional group*". Further, example 1 (pg. 19, paragraph [71]) discloses functionalizing a substrate with a derivatizing composition comprises "97.5 wt. % n-decyltrichlorosilane ("NTS") as a first silane

and 2.5 wt. % undecenyltrichlorosilane ("UTS") as a second silane". Therefore, the scope of the invention as originally disclosed in the specification would not encompass the scope of the limitation of the method step of providing a substrate having a surface displaying olefin functional groups by contacting said surface with a derivatizing composition comprising at least a first silane having an olefin functional group.

If applicants disagree, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the specification.

13. Claims 50-51 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (This is a new matter rejection.)

The instant claims 50 and 51 briefly recite the method of producing an array comprising the method step of "providing a substrate having a surface displaying olefin functional groups by contacting said surface with a derivatizing composition comprising at least a first silane having an olefin functional group wherein said first silane having an olefin functional group is undecenyltrichlorosilane".

The recitation of '*contacting said surface with a derivatizing composition comprising at least a first silane having an olefin functional group wherein said first silane having an olefin functional group is undecenyltrichlorosilane*' claimed in claims 50 and 51, have no clear support in the specification and the claims as originally filed. The specification in page 19 disclosed functionalizing a substrate with a derivatizing composition comprises "97.5 wt. % n-

decyltrichlorosilane ("NTS") as a first silane and 2.5 wt. % undecenyltrichlorosilane ("UTS") as a second silane" (paragraph [71]) is not support for the first silane is 'undecenyltrichlorosilane'. Because the narrow limitation of the specification recites that the first silane is n-decyltrichlorosilane, it does not support the broad limitation of the claim, which recites that the first silane is 'undecenyltrichlorosilane'. Therefore, the scope of the invention as originally disclosed in the specification would not encompass the scope of the limitation of the method step of providing a substrate having a surface displaying olefin functional groups by contacting said surface with a derivatizing composition comprising at least a first silane having an olefin functional group.

If applicants disagree, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the specification.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 7-26, and 44-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al. (US Patent 5,922,617; *filing date 11/12/1997*) and Bensimon et al. (US Patent 5,846,724; *filing date 01/28/1997*).

Wang et al. disclose methods and devices for rapidly screening a large number of events. The devices comprise of a microarray of bound components and the methods comprise of preparing the microarray (col. 2, lines 60-65). The method comprises modifying the surface of the solid substrate by the introduction of functionalities, which would react with the bound components (col. 3, lines 17-25 and 38-45). The functional group that is reactive to the bound components includes "for example, amino groups, activated halides, carboxyl groups, mercaptan groups, epoxides, and the like, may be provided in accordance with conventional ways. The linkages may be amides, amidines, amines, esters, ethers, thioethers, dithioethers, and the like". The bound components include nucleic acids and proteins (col. 3, lines 56-58; col. 5, lines 7-10). The microarray comprises a plurality of different components (col. 2, lines 60-65). The method of Wang et al. further comprises assaying the microarray by detecting the signal produced using a disk scanner (col. 10, lines 16-25 and 50-62). The scanner would be connected to the computer through which the data is collected and process (col. 12, lines 59-67). Additionally with regard to claims 11-15, the type of functional group to be used for covalent bonding of the ligand to the

surface of the substrate would be a choice of experimental design as evidenced by the cited prior art (col. 3, lines 38-45).

The method of Wang et al. does not expressly disclose the method step of contacting said surface with a derivatizing composition comprising at least a first silane having an olefin functional group to produce a substrate having a surface displaying olefin functional groups.

Bensimon et al. disclosed a method of making highly specific surfaces for biological reactions (Abstract; col. 3, lines 40-50). The method comprises functionalizing a support with a variety of silane derivatives that would result in a surface group with a double bond on the substrate (col. 5, lines 31-38) and directly anchoring the molecules of biological interest (col. 4, lines 5-25). The molecules of biological interest include molecules such as DNA, RNA, PNA, proteins, lipids and saccharides (col. 3, lines 44-45).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method by including the step of contacting said surface with a derivatizing composition comprising at least a first silane having an olefin functional group to produce a substrate having a surface displaying olefin functional groups as taught by Bensimon et al. in the method of Wang et al. One of ordinary skill in the art would have been motivated to modify the method by including the step of contacting said surface with a derivatizing composition comprising at least a first silane having an olefin functional group to produce a substrate having a surface displaying olefin functional groups in the method of Wang et al. for the advantage of providing a surface having a reactivity that is highly pH-dependent (Bensimon: col. 6, lines 50-56) since both Wang et al. and Bensimon et al. disclose a method of

functionalizing the surface of the solid for direct attachment of molecule of biological interest (Wang: col. 3, lines 38-45; Bensimon: col. 3, lines 40-50).

Furthermore, one of ordinary skill in the art would have reasonably expectation of success in the method combination of Wang et al. and Bensimon et al. because the method combination would produce a sufficiently specific array of biological molecules wherein the anchoring of the biological molecules does not require specific functionalization of the biological molecule and the ability to detect the isolated target of interest in a sample with a signal to noise ratio that is independent of the number of molecules in the sample.

17. Claims 7-26 and 44-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pirrung et al. (US Patent 5,143,854) and Bensimon et al. (US Patent 5,677,126; *filing date 02/10/1995*).

Pirrung et al. disclose provides methods for forming predefined regions on a surface of a solid support, wherein the predefined regions are capable of immobilizing receptors (col. 8, lines 17-65; col. 30, lines 17-68). The method provides for the use of a substrate with a surface with a Linker molecule. The purpose of the linker molecules is to facilitate receptor recognition of the synthesized polymers on the substrate or a distal end of the linker molecules, a functional group. A single substrate supports comprise more than about 10 different monomer sequences that are randomly distributed on the surface (fig. 10M; col. 24, lines 45-47). When receptors immobilized in this way have a differential affinity for one or more ligands, screenings and assays for the ligands can be conducted in the regions of the surface containing the receptors. Additionally, the attachment of the receptors to the surface of the substrate is from covalent

bonding. The receptors include polynucleotides, nucleic acids, and peptides (col. 6, lines 41-59). The substrate is placed in a microscope detection apparatus for identification of locations where binding takes place (col. 4, lines 14-27).

The method of Pirrung et al. does not expressly disclose the method step of contacting said surface with a derivatizing composition comprising at least a first silane having an olefin functional group to produce a substrate having a surface displaying olefin functional groups.

Bensimon et al. disclosed a method of making highly specific surfaces for biological reactions (Abstract; col. 4, lines 13-23). The method comprises functionalizing a support with a variety of silane derivatives that would result in a surface group with a double bond on the substrate (col. 6, lines 6-13) and directly anchoring the molecules of biological interest (col. 4, lines 24-30, and 45-65). The molecules of biological interest include molecules such as DNA, RNA, PNA, proteins, lipids and saccharides (col. 4, lines 16-18).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method by including the step of contacting said surface with a derivatizing composition comprising at least a first silane having an olefin functional group to produce a substrate having a surface displaying olefin functional groups as taught by Bensimon et al. in the method of Pirrung et al. One of ordinary skill in the art would have been motivated to modify the method by including the step of contacting said surface with a derivatizing composition comprising at least a first silane having an olefin functional group to produce a substrate having a surface displaying olefin functional groups in the method of Pirrung et al. for the advantage of providing a surface having a reactivity that is highly pH-dependent (Bensimon: col. 7, lines 26-32) since both Pirrung et al. and Bensimon et al. disclose a method of

functionalizing the surface of the solid for direct attachment of molecule of biological interest (Pirrung: col. 8, lines 17-65; Bensimon: col. 4, lines 13-23).

Furthermore, one of ordinary skill in the art would have reasonably expectation of success in the method combination of Pirrung et al. and Bensimon et al. because the method combination would produce a sufficiently specific array of biological molecules wherein the anchoring of the biological molecules does not require specific functionalization of the biological molecule and the ability to detect the isolated target of interest in a sample with a signal to noise ratio that is independent of the number of molecules in the sample.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MY-CHAU T TRAN whose telephone number is 571-272-0810. The examiner can normally be reached on Mon.: 8:00-2:30; Tues.-Thurs.: 7:30-5:00; Fri.: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANDREW WANG can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mct
March 7, 2004

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